

JUN 2 - 2005

Ethicon Endo-Surgery, Inc.  
510(k) Premarket Notification for Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control, and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control

K051036

Page 1 of 2

**Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control**  
**510(k) Summary of Safety and Effectiveness**

**Company**

Ethicon Endo-Surgery, Inc.  
4545 Creek Rd.  
Cincinnati, OH 45242

**Contact**

Rachel D. Austin  
Associate I, Regulatory Affairs

**Date Prepared:**

April 22, 2005

**Name of Device**

Trade Name: Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control

Classification Name: Electrosurgical Cutting and Coagulation Device

**Predicate Devices:**

Harmonic ACE with Hand Control cleared under K042777 on 12/01/2004

**Device Description**

The Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control are a sterile, single patient use instrument consisting of a grip housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level). The grip housing has an integrated audible/tactile mechanism for indicating full trigger closure. The instruments have a rotating shaft with a curved blade and clamp arm and is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instruments are available in 14 cm (scissor handle only), 23 cm and 36 cm lengths with a shaft diameter of 5.5 mm and a 15 mm active blade length.

**Indications for Use**

The Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

Ethicon Endo-Surgery, Inc.

510(k) Premarket Notification for Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control, and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control

K051036

Page 2 of 2

The Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

#### **Technological Characteristics**

The Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control are similar to the predicate devices with respect to design and intended use.

#### **Performance Data**

Bench testing was performed to demonstrate that the devices perform as intended.



JUN 2 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Rachel D. Austin  
Associate I, Regulatory Affairs  
Ethicon Endo-Surgery Incorporated  
4545 Creek Road  
Cincinnati, Ohio 45242-2839

Re: K051036

Trade/Device Name: Harmonic Ace™ Curved Shears with Pistol Handle and Hand Control  
and the Harmonic Ace™ Curved Shears with Scissor Handle and  
Hand Control

Regulatory Class: Unclassified

Product Code: LFL

Dated: April 22, 2005

Received: April 25, 2005

Dear Ms. Austin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

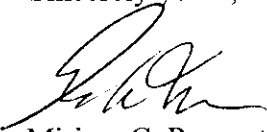
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 – Ms. Rachel D. Austin

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
f Miriam C. Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Ethicon Endo-Surgery, Inc.

510(k) Premarket Notification for Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control, and Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control

## Indications for Use

510(k) Number (if known): K051036

Device Name:

Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control and the  
Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control

Indications for Use:

The Harmonic ACE™ Curved Shears with Pistol Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

The Harmonic ACE™ Curved Shears with Scissor Handle and Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Page 1 of 1

Executive

K051036